--21. (Amended) The method of claim 20, wherein the agent is a peptide, a peptidomimetic compound, a nucleic acid, or a small molecule.--

REMARKS

Claims 1-25 are pending in the subject application. Applicant has herein amended claim 11. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 1-25 will be pending.

Restriction Requirement Under 35 U.S.C. §121

The Examiner required restriction to one of the following allegedly distinct inventions under 35 U.S.C. §121:

I. Claims 1-5, allegedly drawn to purified ERAB polypeptides, classified in Class 530, subclass 350;

II. Claims 6-15, allegedly drawn to isolated nucleic acids that encode ERAB polypeptides, as well as vectors and host cells comprising such, classified in Class 435, subclass 320.1;

III. Claims 16-17, allegedly drawn to antibodies to ERAB polypeptides, classified in Class 530, subclass 387.1;

IV. Claims 18-19, allegedly drawn to transgenic non-human mammals, classified in Class 800, subclass 2;

V. Claims 20-21, allegedly drawn to methods of

testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide, classified in Class 435, subclass 7.1; and

VI. Claim 22, allegedly drawn to a method for treating neurodegeneration with agents that inhibit binding of ERAB to amyloid-beta peptide, and pharmaceutical compositions thereof, classified in Class 424, subclass 130.1+.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason: The Examiner stated that Groups I-IV are directed to products that are physically and functionally distinct that include polypeptides, polynucleotides, antibodies, and transgenic mammals. The Examiner stated that all of these products can be prepared by different processes, such as through chemical synthesis or isolation from natural sources using various isolation/ purification procedures. The Examiner stated that for example, the proteins of Group I and antibodies of Group III are fundamentally different molecules than the polynucleotide molecules of Group II, which in turn can be used to clone the protein, used in gene therapy, or used in isolating the protein of Group I, the antibodies of Group III can be generated by

immunizing mammals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoasays, or as therapeutic agents themselves. The Examiner stated that in contrast, the proteins of Group I can be utilized in making the antibodies of Group III, but not vice versa. The Examiner stated that the transgenic mammals of Group IV can be used to study the effects of expression and activity of the recombinant DNA molecules of Group II, but do not necessarily contain the same isolated DNA molecules/vector sequences of Group II. Moreover, the Examiner stated that the transgenic mammals of Group VII are not required in the products of Groups I-III, and vice versa. Additionally, the Examiner stated that neither the proteins of Group I nor the antibodies of Group III require the vectors and host cells of Group II, and vice versa. The Examiner stated that it is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, the Examiner stated that these groups are distinct and separable for the reasons stated. The Examiner stated that inventions I and V are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §806.05(h)). The Examiner stated that in the instant case, the polypeptide molecules of Group I can be used to generate antibodies. In contrast, the Examiner stated that the method of testing for agents that inhibit binding of

ERAB with amyloid-beta, require amyloid-beta peptide, additional "binding" molecules, as well as appropriate labeling protocols, etc., none of which are required in Group I. Additionally, The Examiner stated that the methods of Group V does not require the products of Groups II-IV, and vice versa. The Examiner stated that although there are no provisions under the section for "Relation of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason: The Examiner stated that Groups V-VI are directed to methods of treating neurodegeneration or directed toward methods of detecting new compounds that inhibit binding of ERAB with amyloid-beta peptide. The Examiner stated that each of these methods require physically and functionally distinct elements. For example, the Examiner stated that the method of Group V requires use of the proteins of Group I, which are entirely different components than those compounds that may inhibit binding of ERAB with amyloid-beta. The Examiner stated that the treatment method of Group V further requires administration protocols and patients with a neuro-degenerative disease, which are not required in the detection method of Group VI. Alternatively, the Examiner stated that the detection of Group VI requires labeling protocols, and different products not required in the treatment methods of Group V, and vice versa. The Examiner stated that these inventions are, therefore, patentably distinct, since one is not required for the other.

The Examiner stated that because these inventions are distinct

for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner stated that applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group V, i.e. claims 20 and 21, allegedly drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide, classified in Class 435, subclass 7.1.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group V from Examiner's Groups I-IV and VI be withdrawn in view of the fact that the claims of Examiner's Group V are not independent of Examiner's Groups I-IV and VI. Applicant maintains that the claims of Examiner's Group V and Examiner's Groups I-IV and VI

do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group V allegedly drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide are related to the claims of Examiner's Groups I-IV and VI in that the claims in all groups are directly related to ERAB/amyloid-beta polypeptide interactions.

The claims of Group V, allegedly drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide are related to the claims of Examiner's Group VI, which are allegedly drawn to a method for treating neurodegeneration with agents that inhibit binding of ERAB to amyloid-beta peptide and pharmaceutical compositions thereof, because of the reliance of both groups on the specific ERAB/amyloid-beta binding as part of their design, operation, and effect. The specification teaches at figures 1B and 1C that ERAB polypeptide(s) specifically interact with the amyloid-beta polypeptide *in vitro*. The specification also teaches at page 37, lines 4-38, and page 38, lines 1-12, that ERAB polypeptide and amyloid-beta peptide interact specifically in the nanomolar range. Further, the specification teaches at page 45, lines 22-38, and page 46, lines 1-10, that in COS cells, co-transfection of a mutant ERAB and mutant amyloid-beta precursor protein resulted in no increased cellular toxicity whereas co-transfection of wild-type ERAB with mutant amyloid-beta precursor

protein increased apoptosis. These data demonstrate that ERAB polypeptide(s) specifically interact with the amyloid-beta peptide and is critical for ERAB potentiation of amyloid-beta cytotoxicity. Therefore, Examiner's Group V, drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide and Examiner's Group VI, drawn to a method for treating neurodegeneration with agents that inhibit binding of ERAB to amyloid-beta peptide and pharmaceutical compositions thereof, utilize the interactions between ERAB/amyloid-beta as part of their design, operation, and effect. Accordingly, applicants request that the Examiner examine Groups V and VI and on the merits.

The claims of Group I, allegedly drawn to purified ERAB polypeptides, Group II, which are allegedly drawn to isolated nucleic acids that encode ERAB polypeptides, as well as vectors and host cells comprising such, Group III, allegedly drawn to antibodies to ERAB polypeptides and Group IV, allegedly drawn to transgenic non-human mammals whose germ and somatic cells contain and express a nucleic acid molecule encoding human ERAB, are related because of the shared structural and functional relationship of the ERAB polypeptide or portions thereof identified in all claims in Groups I, II, III and IV. The claims of Examiner's Group V, allegedly drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide, may utilize the purified ERAB polypeptides, isolated nucleic acids that encode ERAB, antibodies to ERAB, or transgenic non-human mammals whose germ and somatic cells contain and express a nucleic acid molecule encoding human ERAB of

Examiner's Groups I, II, III and IV as part of its overall design, operation, and effect. Therefore, the claims of Examiner's Groups I, II, III, IV and V are related. Accordingly, Examiner's Groups I, II, III and IV are related to Group VI through their respective relation to the claims of Group V.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group V, claims 20 and 21 allegedly drawn to methods of testing/evaluating agents to inhibit binding of ERAB to amyloid-beta peptide will reveal whether any prior art exists as to a method for treating neurodegeneration with agents that inhibit binding of ERAB to amyloid-beta peptide(Group VI) and purified ERAB polypeptides, isolated nucleic acids that encode

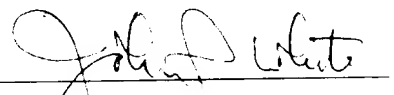
ERAB, antibodies to ERAB, and transgenic non-human mammals that express ERAB (Groups I-IV). Since there is no burden on the Examiner to examine Groups I-VI in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 1-25 define a single inventive concept. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-25 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invite the Examiner to telephone him at the number provided below.

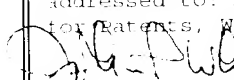
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



10/29/01

John P. White — Date
Reg. No. 28,678

EXHIBIT A

--21.(Amended)The method of claim 20 [21], wherein the agent is [comprises] a peptide, a peptidomimetic compound, a nucleic acid, or a small molecule.--